PenTips

#177: GUDID Tracking

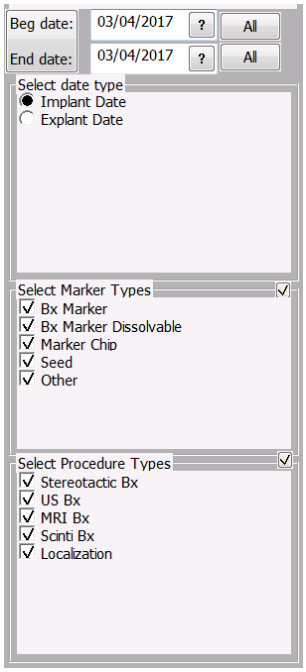
GUDID Tracking System

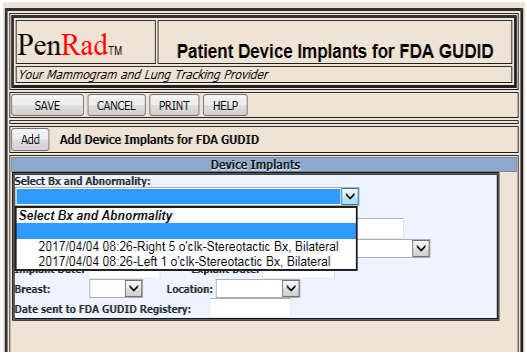
With the release of a new FDA regulation, implanted devices are to be tracked by device, lot code, patient, body location, and implant date, plus a date if explanted as well. Biopsy marking clips, self-absorbing markers, chips and seeds are all included. Many of the devices have a 60 digit alpha numeric coding system.

PenRad has prepared a Patient Device tracking module to collect implanted devices.

During a biopsy or localization procedure, the GUDID information is collected for each device implanted. GUDID information that is entered is included in the narrative report, fulfilling another regulation component.

For facilities not using PenRad's narrative reports, GUDID data is catalogued via the Devices Implanted button located on the Patient Maintenance screen. The user then selects the procedure type that populates the implant date, enters the location, and enters the device type and GUDID #. If a device is removed, for example; by lumpectomy, the explant date can be captured.

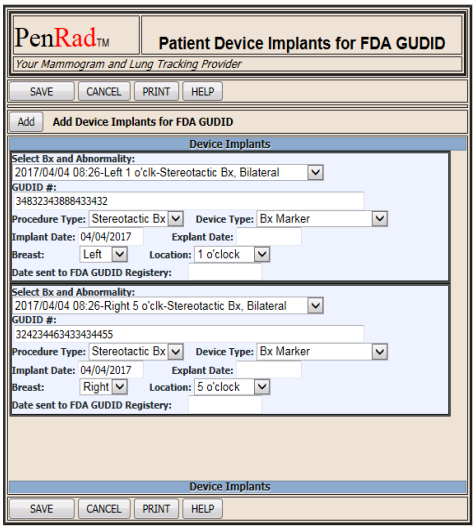




For compliance with new regulation, PenRad added administrative report FDA GUDID Device Implants (left).

This report facilitates custom searching capabilities for recalled devices or devices of concern, by manufactures, by lot numbers, and by serial numbers for patient identification.

During narrative report generation, a location list is auto created where marker or seed is referenced (left), then only GUDID # needed (below).



When the FDA readies a national database for GUDID data, this data can be submitted via this report, allowing FDA to contact responsible parties for concerns and resolution.

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Recommendation for product development?

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